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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,132	06/19/2003	Thomas A. Miller	24852-501 CIP	8627
35437	7590	09/12/2006	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017				VALENROD, YEVGENY
ART UNIT		PAPER NUMBER		
				1621

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/600,132	MILLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yevgeny Valenrod	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 29 June 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-137 is/are pending in the application.
- 4a) Of the above claim(s) 40-137 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-39 is/are rejected.
- 7) Claim(s) 20-36 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 3/14/05; 10/05/05; 7/25/06; 4/06/04
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicant's election of Group I, claims 1-39 in the reply filed on June 29 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The non-elected claims are withdrawn from further consideration.

### ***Claim Objections***

Claims 28-36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 28 depends on a multiple dependent claim 27 and claims 29-36 directly or indirectly depend on claim 28. See MPEP § 608.01(n). Accordingly, the claims 28-36 have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Stowell et al. (*J. Med. Chem.* 1995, 38, 1411-1413).

Stowell et al. disclose suberanilohydroxamic acid (same as suberoylanilide hydroxamic acid, as used in the instant claims, SAHA) that was prepared as a white solid free of impurities (page 1413, column 1 lines 19-21). Said SAHA has a melting point of 159-160.5, which is very close to the melting point range extracted from applicants DSC thermogram (162-166). The SAHA disclosed by Stowell differs from the claim in that the reference is silent on crystalline form. However the applicants must show that their crystalline form really is different from the one prepared by Stowell et al. MPEP 2112 states:

**“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE  
UPON THE DIS-COVERY OF A NEW PROPERTY**

“.... Claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)”

In the case at hand the unknown property is the particular crystalline form of SAHA. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

**“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC**

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but

the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

Again the "CHARACTERISTIC" on which the prior art is silent is the crystalline form.

It is therefore the Examiners position that SAHA disclosed by Stowell is the same form as the one claimed by the applicant. Applicant is invited to provide evidence to the contrary.

Concerning claim 28, on page 1412, column2, lines 3-15 Stowell et al. disclose a pharmaceutical composition comprising SAHA and a pharmaceutically acceptable carrier, DMSO.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stowell et al. (*J. Med. Chem.* 1995, 38, 1411-1413) in view of Kabadi (EP 0 547 000 A1).

The instant claims are directed towards a composition comprising SAHA Form 1. Additional limitations include: tablet, capsule, or gelatin capsule; form suitable for oral

administration, intravenous administration or other methods of administering as listed in claim 34; immediate or slow dosage release form; further comprising microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

*Scope of prior art*

Stowell et al. teach a solid form of SAHA, a pharmaceutical composition comprising SAHA (Dissolved in DMSO, a pharmaceutically acceptable carrier, page 1412 lines 3-15) and its pharmacological potential as an agent for the treatment of prostate cancer (page 1412, lines 16-24).

*Ascertaining the difference between prior art and the instant claims*

Stowell et al. teach SAHA and a pharmaceutical composition comprising SAHA and also suggest its use in treatment of prostate cancer. However they fail to teach the compositions claimed in the instant claims 29-39.

*Secondary reference*

Kabadi teaches a pharmaceutical composition for oral administration comprising fluvastatin (active ingredient), microcrystalline cellulose, croscarmellose sodium and magnesium stearate (page 9, example 4). The % composition of the said ingredients is discussed of page 4. Microcrystalline cellulose (binder/filler), about 1-65 wt.%, croscarmellose sodium (disintegrant), about 1-5 wt.%, and magnesium stearate (lubricant), about 0.1-2 wt.%

*Obviousness*

Microcrystalline cellulose, croscarmellose sodium and magnesium stearate are commonly used additives in pharmaceutical compositions that are to be administered

orally. The above substances are well known to those skilled in the art as physiologically inactive ingredients that are usually used as binder, disintegrant and lubricant (respectively). The % composition of the said ingredients, as recited in the instant claim 38, fall within the ranges taught by Kabadi (page 4 line 24-28 and 38-40. Kabadi also exemplifies their use together in an oral fluvastatin tablet (page 9, example 4). One of ordinary skill in the art would find it obvious to use the combination of physiologically inactive ingredients taught by Kabadi in a pharmaceutical composition for oral administration of SAHA. One of ordinary skill would also be able to determine through routine experimentation the amount of the active ingredient SAHA to be administered to a patient. Claims 37 - 39 are therefore rejected under 35 USC 103.

Claims 29 – 36 do not require the secondary reference. Making tablets capsules and gelatin capsules or dissolving/suspending a compound for intravenous administration or other modes of administering a compound is common in the art. Determining the specific dosage or route of administration is routine and well within ordinary level of skill in the art.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 28, 29, 31, 32, 37, 38 and 39 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 156-159 of copending Application No. 10/379,149. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

Claims 1-136 are pending in the application.

Claims 40-136 are withdrawn from further consideration as directed to non-elected subject matter:

Claims 1-39 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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